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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,953	01/23/2004	Xianqi Kong	NBI-193	5062
959	7590	04/27/2006	EXAMINER	
LAHIVE & COCKFIELD 28 STATE STREET BOSTON, MA 02109			NOLAN, JASON MICHAEL	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 04/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/763,953

Applicant(s)

KONG ET AL.

Examiner

Jason M. Nolan, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 23-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8 is/are rejected.
- 7) ☒ Claim(s) 23-26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-8 and 23-26 are currently pending in the instant application. **Claims 9-22** are canceled.

Information Disclosure Statement

Applicants have not filed an information disclosure statement (IDS).

Response to Restriction

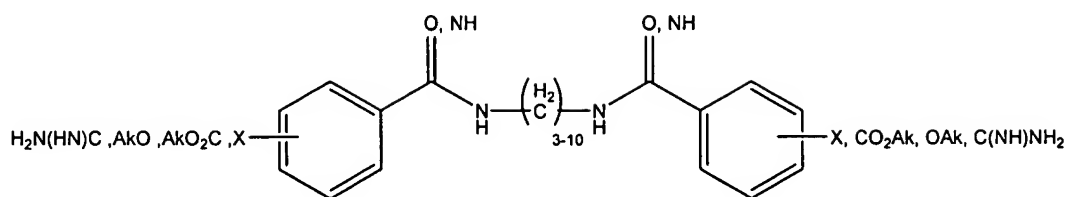
Applicants' election without traverse of **Group I, Claims 8 and 23-26 (Claim 26** was left out of the restriction requirement, but is now grouped with the other composition claims) is acknowledged. The Examiner also acknowledges the election of species disclosed as 4,4'-(pentamethylenediamidino)di(*p*-methoxybenzene), hydrochloride salt.

Status of the Claims

Claims 1-8 and 23-26 are pending in this application. **Claims 1-7 and 8 (in part)** are withdrawn from further consideration by the Examiner as being drawn to non-elected inventions under 37 CFR § 1.142(b). The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search and examination considerations. In addition, a reference that anticipates one invention would not render obvious the other invention.

The scope of the invention of the elected subject matter is the compounds and compositions in **Claims 8 (in part) and 23-26** and the corresponding species: 4,4'-(pentamethylenediamidino)di(*p*-methoxybenzene), hydrochloride salt.

As a result, the examined subject matter is the compounds and compositions of **Claim 8**, which share the same core structure shown below. This includes the 2nd, 4th-8th, 10th, and 14th-15th compounds in **Claim 8**, in addition to **Claims 23-26**.



As a result of the election and the corresponding scope of the invention, identified supra, the remaining subject matter of **Claim 8 (in part)** is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected inventions.

The scope of the invention of the non-elected and non-examined subject matter are the 1st, 3rd, 9th, and 11th-13th compounds and compositions of **Claim 8**, in addition to **Claims 1-7**.

The withdrawn compounds contain the variety of cores, which are patentably distinct from the elected and examined core, and are chemically recognized to differ in structure, function, and reactivity. Therefore, the subject matter, which has been withdrawn from consideration as being *non-elected* subject matter materially, differs in structure and composition from the elected/examined subject matter so that a reference that anticipates the elected/examined subject matter would not render obvious the *non-elected* subject matter.

This recognized chemical diversity of the functional groups is apparent by the different fields of search required for the *non-elected* species versus the elected compounds. All compounds falling outside the search strategy of the elected compound and the structure shown above are heretofore directed to *non-elected* subject matter and are withdrawn from consideration under 35 U.S.C. § 121 and 37 C.F.R. § 1.142(b).

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

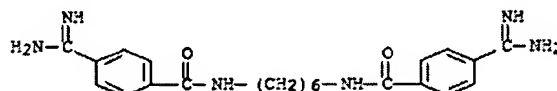
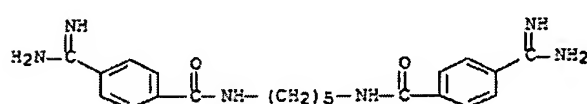
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. *Determining the scope and contents of the prior art.*
2. *Ascertaining the differences between the prior art and the claims at issue.*
3. *Resolving the level of ordinary skill in the pertinent art.*
4. *Considering objective evidence present in the application indicating obviousness or nonobviousness.*

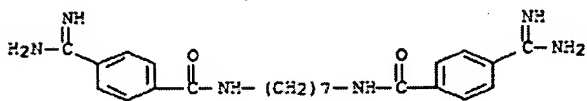
Claim 8 (in part: the 6th, 7th, 8th, 10th, 14th, and 15th compounds) is rejected under 35 U.S.C. § 103(a) as being unpatentable over Chalifour *et al.* (WO 2003017994), taken alone.

Determination of the scope and content of the prior art (MPEP § 2141.01)

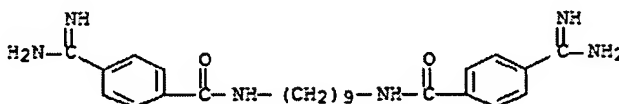
Chalifour *et al.* teaches the following compounds:



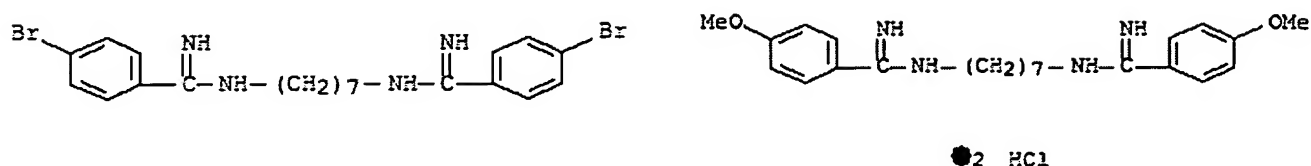
●2 HCl



●2 HCl

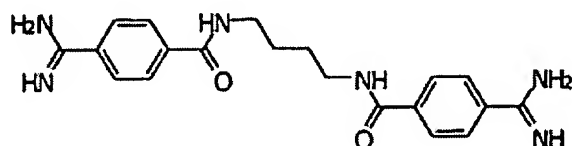


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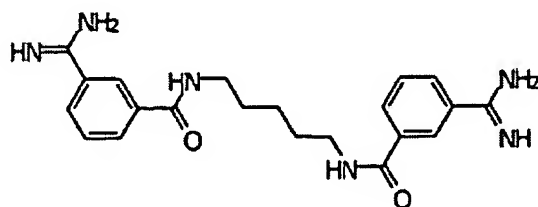


Ascertainment of the difference between the prior art and the claims (MPEP § 2141.02)

The first four compounds shown on the previous page are all homologous compounds, differing by the length of the alkyl chain connecting the amido-aryl moieties. The alkyl chains are 5, 6, 7, and 9 carbons in length and this variation in chain length provides the difference from the 15th compound in **Claim 8** of the instant application, which has a alkyl chain length of 4, shown below.

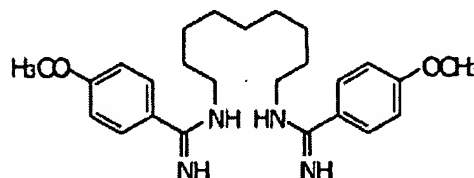
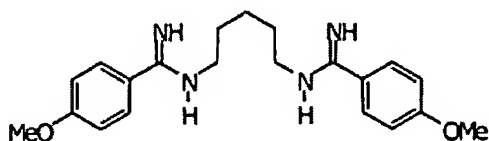


The difference between the first compound on the previous page and the 14th compound in **Claim 8**, shown below, is the position of the aryl substituents. The known compounds taught be Chalifour *et al.* are all *para*-substituted, whereas the aryl substituents of the compound in the instant application is *meta*-substituted.

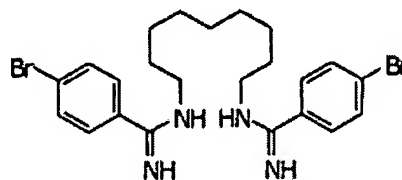
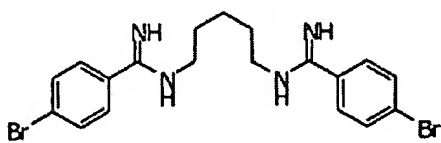


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The difference between the *para*-methoxy substituted compounds in the instant application (8th and 10th compounds of **Claim 8**) and compound taught be Chalifour *et al.* shown on the previous page is again the length of the alkyl chain. The two compounds claimed in the instant application (shown below) have chain lengths of 5 and 9 carbons, whereas the compound above has a alkyl length of 7 carbons.



The difference between the *para*-bromine substituted compounds in the instant application (6th and 7th compounds of **Claim 8**) and compound taught be Chalifour *et al.* shown on the previous page is again the length of the alkyl chain. The two compounds claimed in the instant application (shown below) have chain lengths of 5 and 9 carbons, whereas the compound above has a alkyl length of 7 carbons.



Finding of prima facie obviousness--rational and motivation (MPEP § 2142-2413)

To those skilled in the chemical art, one homolog is not such an advance over an adjacent member of a series because chemists knowing properties of one member of the series would in general know what to expect in adjacent members. *In re Henze*, 85 USPQ 261 (1950). The instant claimed compounds (the 6th, 7th, 8th, 10th, and 15th

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compounds in **Claim 8**) would have been obvious because one skilled in the art would have motivated to prepare homologs of the compounds taught by Chalifour *et al.* with the expectation of obtaining compounds which could be used in pharmacology. Therefore, the instant claimed compounds would have been suggested to one skilled in the art.

One skilled in the art would have found the claimed compound (the 14th compounds in **Claim 8**) prima facie obvious because it is well established that nothing unobvious is seen in substituting the known claimed isomers, as taught by Chalifour *et al.*, since such structurally related compounds suggest one another and would be expected to share common properties absent a showing of unexpected results. *In re Norris*, 84 USPQ 458 (1950).

Claim Objections

Claim 8 is objected to for containing *non*-elected subject matter.

Claims 23-24 are objected to for depending on a rejected base claim.

Claims 25-26 are objected to under 37 CFR 1.75 as being a substantial duplicate of **Claims 23-24**. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Tidwell *et al.* WO 2005033065 and Boykin *et al.* WO 2003103598.

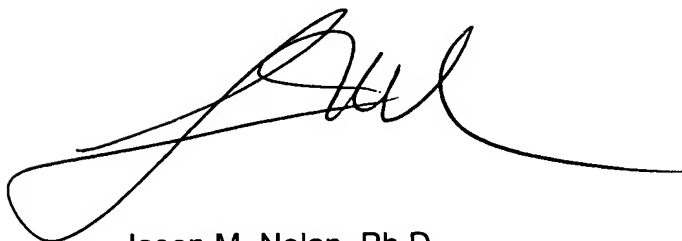
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Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jason M. Nolan, Ph.D.** whose telephone number is **(571) 272-4356**. The examiner can normally be reached on Mon - Fri (9:00 - 5:30PM) or via electronic mail at **Jason.Nolan@uspto.gov**.

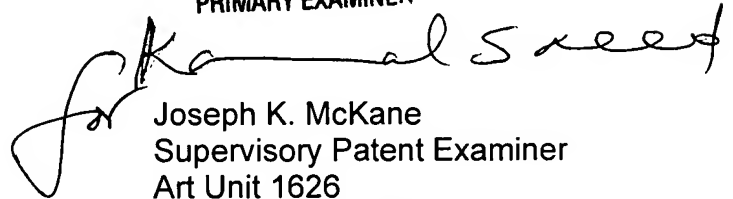
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph McKane** can be reached on **(571) 272-0699**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for +published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jason M. Nolan, Ph.D.
Examiner
Art Unit 1626

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER



Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626
Date: April 24, 2006